



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0307]

Agency Information Collection Activities; Proposed Collection; Comment Request; Antiparasitic Drug and Resistance Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's "Antiparasitic Drug and Resistance Survey."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality,

utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Antiparasitic Drug and Resistance Survey--21 CFR Part 514.4 (OMB Control Number 0910-NEW)

Resistance of parasites to one or more of the major classes of FDA approved antiparasitic drugs is a documented problem in cattle, horses, sheep, and goats in the United States. The results from this survey will provide FDA information that can be used to make decisions about future approaches to antiparasitic drugs. FDA will make the results of the survey publicly available.

FDA plans to survey members of veterinary professional organizations using an Internet-based survey instrument. The questions in the survey are designed to elicit professional opinions regarding the use of antiparasitic drugs and the awareness of antiparasitic drug resistance. The survey will query subjects on topics including: (1) Awareness of the issues related to antiparasitic resistance, (2) methods currently being used to detect and/or monitor for antiparasitic resistance, (3) management practices being used or recommended to manage or reduce antiparasitic resistance, and (4) labeling and marketing considerations for antiparasitic drugs.

FDA published a 60-day notice in the Federal Register on July 13, 2010 (75 FR 39948), requesting public comment on the proposed survey, and published a 30-day notice on May 23, 2011 (76 FR 29762), and submitted the Information Collection Request (ICR) package to OMB. FDA subsequently entered into study design and development discussions with OMB officials. OMB decided that FDA should resubmit the study with a new 60-day notice and begin a new

ICR package. This document responds to that request. Substantial revisions to the scope and content of the survey were also made based on information presented at the Antiparasitic Drug Use and Resistance in Ruminants and Equines Public Meeting (77 FR 7588, February 13, 2012; Docket No. FDA-2012-N-0102).

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

Portion of Study	No. of respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Pre-test	5	1	5	.5	2.5
Survey	650	1	650	.5	325
Total					327.5

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA will conduct a pre-test of the survey with five respondents, and it is estimated that it will take 30 minutes (0.5 hour) to complete the pretest, for a total of 2.5 hours. We estimate that 650 respondents will complete the survey. It is estimated that it will take a respondent 30 minutes (0.5 hour) for a total of 325 hours. Thus, the total estimated annual reporting burden is 327.5 hours. FDA's burden estimate is based on prior experience with consumer surveys that are similar.

Dated: November 28, 2012.

Leslie Kux,

Assistant Commissioner for Policy.